

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

In re the Application of

Inventors : **Craig S. Aman**
Application No. : **09/739,357**
Filed : **December 19, 2000**
For : **WEB ENABLED MEDICAL DEVICE TRAINING**

APPEAL BRIEF

On Appeal from Group Art Unit 3714

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I. REAL PARTY IN INTEREST

The real party in interest is Koninklijke Philips Electronics N.V., Eindhoven, The Netherlands, successor by assignment from the original assignee, Agilent Technologies.

II. RELATED APPEALS AND INTERFERENCES

A first appeal in this case was filed August 3, 2005 and was briefed by applicant. This appeal was terminated when prosecution of the case was reopened by the Office action mailed June 6, 2006. A second appeal was filed on September 6, 2007 and briefed on November 6, 2007. Again prosecution was reopened, resulting in this third appeal filed July 29, 2008. There are no related interferences.

III. STATUS OF CLAIMS

Claims 1-25 and 38-47 are pending in the application and stand rejected a fourth time. Claims 26-37 and Claims 48-49 were previously canceled. Claims 1-25 and 44-47 are withdrawn. The claims being appealed are Claims 38-43.

IV. STATUS OF AMENDMENTS

No amendment was filed in response to the Office action mailed January 29, 2008.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The present invention is a computer simulation method for instructing an operator on the use of a medical device. Computer simulation programs are well

known. The Board is no doubt familiar with the classic "Flight Simulator" program by which a user can "operate" the controls of a plane shown on the screen and "fly" the plane. These concepts have been applied to more serious endeavors such as training medical professionals in the use of medical instruments and the treatment of patients. The art cited in this case is well representative of such applications. Some are in a question- and-answer format. In some of these, the user is asked to select the next medical instrument to be used in a procedure. More advanced programs permit the user to "grasp" a simulated medical instrument and actually apply it to a simulated patient. Some show a video of the procedure to train the user in the result of use of the instrument. Still others use physical models with sensors. As the user manipulates the physical model, the manipulation is sensed and the results of the manipulation are shown on a computer screen. For a medical instrument, a user may be shown simulated controls of the instrument and be asked to manipulate the controls properly.

But for some medical instruments, simply manipulating the controls may not be enough to train the user in the use of the instrument. The defibrillator described in the present application is one such medical instrument. For a defibrillator the user must not only manipulate the controls of a defibrillator but must also know how to use the first aid instruments which are a part of the device. In the case of a defibrillator the user must be instructed in how to properly place the defibrillator's electrode pads on the chest of the patient as well as operate the defibrillator's controls. Such complete training is especially important for an automatic external defibrillator as described in this application, for AEDs must often be used by first responders at the scene of a cardiac arrest, laypersons who are not medical professionals and whose

intervention in the airport or office building is essential to save a victim before trained medical professionals arrive. Full and complete instruction on the AED is essential for such individuals. The present invention is directed to a computerized medical device simulation method which allows the user to interact with both the simulated controls of the instrument, and to simulate the use of the instrument's first aid devices on a simulated patient.

The subject matter of the claimed invention as per Claim 38 and its dependent claims is a method for providing instruction on the use of a medical device to a user computer. The inventive method may be carried out by a server computer 102 which communicates over a network 104 to a trainee computer 106 (Claims 38 preamble: "user computer") as shown in Fig. 1 and described on page 5, lines 13-25. The method begins in the illustrated example with a request for instruction on use of a medical device from the trainee computer 106 running a medical device training program 202 as described at column 7, lines 18-25. In the illustrated example the medical device is an automated external defibrillator. The request causes a series of operational steps to be performed by the server 102. The server responds by providing a list 502 of instructional topics associated with the defibrillator. This list is displayed on the graphical user interface of the trainee computer 106 as shown by the training topic screen in the constructed embodiment of Fig. 5 and discussed on page 9, lines 13-21. As explained in this passage, selecting an item on the list 502 will cause a related list 602 of instructional subtopics to appear on the graphical user interface. Such a subtopic screen display 600 is shown in Fig. 6 and is easily accessed in this embodiment because topics on the first list are constructed as links. The subtopic screen display 600 is described on page 8, line 23 through page 9, line 9. When the

trainee user selects one of the instructional subtopics 602 a plurality of instructional graphical user interface screens 700-1100 pertaining to the subtopic are presented. These screens provide simulated hands-on operation of the defibrillator by providing a medical device control object simulating a control of the defibrillator (Claim 38, element a)) and a medical device first aid object (Claim 38, element b)) of the defibrillator such as electrode pads. For instance, Fig. 8 displays medical device first aid instrument objects of the defibrillator, simulated electrode pads 820, which the trainee user is asked to place on the chest of the simulated patient. The user selects the pads 820 on the screen and manipulates them (Claim 38, element g)) to place and position the pads in the proper locations on the patient's chest as described on page 9, lines 25-29. The trainee user can also click on the "AUDIO" icon to hear the actual audio instructions played by the defibrillator during its use as described on page 10, lines 14-15 and page 10, line 24 through page 11, line 13. The user can observe a live video of the ECG trace as shown in Fig. 9 and, if a shock is advised, can press a medical device control object of the defibrillator, the simulated orange shock button 1024, as shown in Fig. 10. For each simulation, interaction feedback is provided (Claim 38, element c) to assess the trainee's competence in operating the defibrillator controls and manipulating the simulated electrode pads to correctly place them on the simulated patient as shown in Fig. 9. The feedback indicates to a trainee user whether a simulated interaction is appropriate, as well as the correctness of the user interaction with the medical device control object and the medical device first aid instrument object (Claim 38, element c) as described on page 8, lines 4-13. The tutorial is accompanied by context-related text, images and videos illustrating use of the medical

device and first aid object with patients as shown in Fig. 7 and Fig. 10 at 710 and 714 and described on page 10.

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether Claims 38-40 stand correctly rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. 6,537,714 (Melker et al.) in view of U.S. Pat. 6,126,450 (Mukai et al.).

2. Whether Claims 39-40 stand correctly rejected under 35 U.S.C. §102(e) as being anticipated by Melker et al.

3. Whether Claims 41-43 stand correctly rejected as being unpatentable over Melker et al. in view of Mukai et al. and further in view of U.S. Pat. 5,791,907 (Ramshaw et al.)

VII. ARGUMENT

A. Rejection of Claims 38-40 as unpatentable over Melker et al. in view of Mukai et al.

Claim 38 is the only independent claim on appeal. Claim 38 describes a method for providing instruction on the use of a medical device to a user computer, the method comprising a) providing a medical device control object in a first graphical user interface, the medical device control object simulating a control of the medical device; b) providing a medical device first aid instrument object in the first graphical user interface or a second graphical user interface, the medical device first aid object simulating a first aid component of the medical device; g) allowing a trainee to interact with the medical device control object and medical device first aid

instrument object by manipulation of the displayed medical device control object and medical device first aid instrument object in the first or second graphical user interface; and c) providing feedback in response to interacting with the medical device control object and medical device first aid instrument object, the feedback indicating the correctness of the interaction with the medical device control object and the medical device first aid instrument object. An embodiment of this invention provides complete training for a medical device: both the operation of its controls and the use of its first aid instrument components with a patient. In the case of a defibrillator, for example, the first aid instrument object would be the electrode pads and the control object would be the defibrillator controls. The instruction method will teach the student on the proper operation of the defibrillator controls and on correct placement of the defibrillator's electrode pads on the patient, for instance. Correct placement of electrode pads is essential for a successful defibrillation. If the student would attempt to analyze the ECG or measure patient impedance before attaching the pads to the patient, for instance, the instructional program would alert the student that the intended analysis or measurement was incorrect because the electrode pads have to be properly attached to the patient before either analyzing the ECG or measuring patient impedance.

Melker et al. describe a training computer called a "PTT" which may be embodied as a handheld "tablet" computer. The PTT provides training by instructional modules and interactive modules. The interactive module displays the controls of a medical device on the PTT and also the output of the device such as a display. See column 6, lines 3-19 of Melker et al. Alternatively, the PTT connects to an actual medical device via an RS-232 port and receives input signals from actuation

of the controls of the device. See column 6, lines 20-27 of Melker et al. In either case the PTT tracks the operation of the controls to gauge the student's ability to operate the controls of the device. See column 3, line 35 and column 7, lines 50-63 of Melker et al. Thus, the PTT measures the student's skill by his or her ability to operate the controls of the actual or simulated medical device. There is no suggestion of training by having a student manipulate both medical device control objects and first aid instrument objects of the medical device as called for by Claim 38. The Examiner admits as much at the bottom of page 5 of the Office action of July 13, 2007.

To make up for this deficiency, the Examiner cites Mukai et al. Mukai et al. is directed to obviating the need for a physical model of the patient as required by some simulators and instead to simulate the patient on a computer. See column 17, lines 60-64 of Mukai et al. The Mukai et al. simulator simulates the patient as shown by their example of the simulation of an eyeball. The user then operates a control to manipulate a simulated instrument such as a knife or "phaco" tool or electrocautery to perform treatment on the simulated eyeball. See column 7, line 37 through column 8, line 59. Mukai et al. are thus simulating an instrument and not the controls of a medical device. Furthermore, there is no suggestion of simulating, in addition to the controls, the use of a first aid object associated with the medical device. Only the manipulation of a simulated medical instrument is suggested by Mukai et al. Mukai et al. fail to supply the subject matter missing from Melker et al. with regard to the present claimed invention. It is therefore respectfully submitted that the combination of Melker et al. and Mukai et al. cannot render the invention of Claim 38 unpatentable.

Claims 39 and 40 both depend from Claim 38. It is respectfully submitted that these claims are patentable over Melker et al. and Mukai et al. by reason of this dependency.

B. Rejection of Claims 39-40 as being anticipated by Melker et al.

As just stated, Claims 39 and 40 both depend from Claim 38 and thus include all of the limitations of Claim 38. By this rejection of anticipation, the Examiner is contending that all of the limitations of these claims can be found in Melker et al. But on page 6 of the January 29, 2008 Office action, the Examiner admits that "Melker does not specifically disclose a medical device control object simulating a control of a medical device." By this admission the Examiner acknowledges that Melker et al. cannot anticipate Claims 39 and 40. But beyond that, there is no suggestion in Melker et al. of providing and allowing manipulation of both a medical device control object and a medical device first aid instrument of the medical device as recited in step g) of Claim 38 and included by dependency in both of Claims 39 and 40. It is respectfully submitted that for all of these reasons Melker et al. cannot anticipate Claims 39 and 40.

C. Rejection of Claims 41-43 as unpatentable over Melker et al. in view of Mukai et al. and further in view of Ramshaw.

The shortcomings of Melker et al. and Mukai et al. with regard to the present invention have been discussed above. To these patents the Examiner adds Ramshaw et al., which describes a computerized training system for surgical procedures. As shown in Figs. 5-11 of Ramshaw et al., this surgical training system asks the student to identify instruments which are to be used for various steps of the surgical procedure. In Figs. 5A and 5B, the student is expected to identify a hemostat to be

used for the next step of the procedure. When the student correctly identifies the next instrument, the system plays a video showing the use of the instrument in the next step as shown in Figs. 7-8. The student is not expected to manipulate a simulated or actual instrument, only to select it. And there are no device controls to manipulate, only the making of a selection. Thus, Ramshaw et al. is cumulative of Mukai et al. only less so, for there is no ability to manipulate a simulated instrument in Ramshaw et al. If the student selects the proper instrument from a list of instrument names, a video showing use of the instrument in the procedure is played. There is no showing or suggestion in Ramshaw et al. of providing and allowing manipulation of both a medical device control object and a medical device first aid instrument of the medical device as recited in step g) of Claim 38 and included by dependency in dependent Claims 41-43. It is therefore respectfully submitted that Ramshaw et al. fails to supply the subject matter missing from Melker et al. and Mukai et al. that are needed to render Claim 38 and its dependent claims unpatentable. An embodiment of the present invention will provide a fully, more complete, and more realistic training scenario of a medical device, its simulated controls, and its simulated first aid components than is possible with any combination of Melker et al., Mukai et al., and Ramshaw et al.

VIII. CONCLUSION

Based on the law and the facts, it is respectfully submitted that Claims 38-43 are patentable over the combination of the Melker et al., Mukai et al., and Ramshaw et al. patents. Accordingly, it is respectfully requested that this Honorable Board reverse the grounds of rejection stated in the January 29, 2008 Office action being appealed.

Respectfully submitted,

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APPENDIX A: CLAIMS APPENDIX

- 1) (Withdrawn) A method for providing instruction on the use of a medical device to a user computer, the method comprising:
 - a) receiving a request for instruction on the use of the medical device over a network, the request originating from the user computer;
 - b) providing a first graphical user interface having a list of instructional topics associated with the medical device to the user computer in response to the request;
 - c) providing a second graphical user interface having a list of instructional sub-topics associated with an item on the list of instructional topics to the user computer in response to receiving a request for the item on the list of instructional topics from the user computer;
 - d) providing a plurality of instructional graphical user interfaces having instructions pertaining to an item on the list of instructional sub-topics to the user computer in response to receiving a request for the item on the list of the instructional sub-topics from the user computer, at least one of the first, second and plurality of instructional graphical user interfaces including at least one interactive simulation object with which interaction simulates operating controls or device instruments of the medical device; and
 - e) generating a feedback in response to interacting with the interactive simulation object indicating (i) whether a particular interaction is appropriate under given conditions; and (ii) the correctness on the use of the medical device.
- 2) (Withdrawn) The method according to claim 1, wherein the medical device is an Automatic External Defibrillator (AED).
- 3) (Withdrawn) The method according to claim 1, wherein the list of instructional topics include at least a utility of the medical device item, an operation of the medical device item, a device troubleshooting item and a device maintenance item.

- 4) (Withdrawn) The method according to claim 1, further comprising:
 - f) providing an audio in at least one of the graphical user interfaces.
- 5) (Withdrawn) The method according to claim 1, further comprising:
 - f) providing linear and non-linear navigation from at least one of the graphical user interfaces to another of the graphical user interfaces.
- 6) (Withdrawn) The method according to claim 1, wherein the instructional information in each of the plurality of instructional graphical user interface includes a text description of one or more operational steps pertaining to the selected item on the list of instructional sub-topics.
- 7) (Withdrawn) The method according to claim 6, further comprising:
 - f) providing in one or more of the plurality of instructional graphical user interfaces one or more still images illustrating the text description of the one or more operational steps.
- 8) (Withdrawn) The method according to claim 6, further comprising:
 - f) providing in one or more of the plurality of instructional graphical user interfaces an interactive animation illustrating the text description of the one or more operational steps.
- 9) (Withdrawn) The method according to claim 6, further comprising:
 - f) providing in one or more of the plurality of instructional graphical user interfaces a video illustrating the text description.
- 10) (Withdrawn) The method according to claim 6, wherein each of the plurality of instructional graphical user interfaces is provided based on the order in which the one or more operational steps in the text description would be performed during the proper operation of the device.

- 11) (Withdrawn) The method according to claim 10, wherein the medical device is an Automatic External Defibrillator (AED).
- 12) (Withdrawn) The method according to claim 10, further comprising:
- f) providing in one or more of the plurality of instructional graphical user interfaces an interactive animation illustrating the text description of the one or more operational steps.
- 13) (Withdrawn) The method according to claim 12, wherein user interaction is required for the animation illustrating the text description of the one or more operational steps.
- 14) (Withdrawn) A system for providing instruction on the use of a medical device, the system comprising:
- a) a network;
 - b) a user computer coupled to the network for requesting instructional information on the use of the medical device; and
 - c) a server coupled to the network;
- wherein the server provides a first graphical user interface having a list of instructional topics associated with the medical device to the user computer in response to the request for instruction, provides a second graphical user interface having a list of instructional sub-topics associated with an item on the list of instructional topics to the user computer in response to receiving a request for the item on the list of instructional topics from the user computer, provides a plurality of instructional graphical user interfaces having instructional information pertaining to an item on the list of instructional sub-topics to the user computer in response to receiving a request for the item on the list of the instructional sub-topics from the user computer, at least one of the first, second, and plurality of instructional graphical user interfaces including at least one interactive simulation object with which interaction simulates operating controls or device instruments of the medical devices, and generates a feedback in response to interacting with the interactive simulation object indicating (i) whether a particular interaction is

appropriate under given conditions; and (ii) the correctness on the use of the medical device.

15) (Withdrawn) The system according to claim 14, wherein the medical device is an Automatic External Defibrillator (AED).

16) (Withdrawn) The system according to claim 14, wherein the network is the Internet or an Intranet.

17) (Withdrawn) The system according to claim 14, wherein the list of instructional topics include at least a utility of the medical device item, an operation of the medical device item, a device troubleshooting item and device maintenance item.

18) (Withdrawn) The system according to claim 14, further comprising:

d) an audio object provided in at least one of the graphical user interfaces permitting the user to listen to an audio.

19) (Withdrawn) The system according to claim 14, further comprising:

d) a linear navigation object and a non-linear navigation object provided in at least one of the graphical user interfaces permitting the user to navigate from the at least one of the graphical user interface displays to another of the graphical user interfaces.

20) (Withdrawn) The system according to claim 14, wherein the instructional information includes a text description of one or more operational steps pertaining to the selected item on the list of instructional sub-topics.

21) (Withdrawn) The system according to claim 20, further comprising:

d) at least one still image object provided in each of the plurality of instructional graphical user interfaces for illustrating the text description of the one or more operational steps.

- 22) (Withdrawn) The system according to claim 20, further comprising:
- d) an interactive animation object provided in the at least one instructional graphical user interfaces for illustrating the text description of the one or more operational steps.
- 23) (Withdrawn) The system according to claim 20, further comprising:
- d) a video object provided in at least one of the plurality of instructional graphical user interfaces for illustrating the text description of the at least one instructional graphical display.
- 24) (Withdrawn) The system according to claim 20, wherein each of the plurality of instructional graphical user interfaces is provided based on the order in which the one or more operational steps in the text description would be performed during the proper operation of the device.
- 25) (Withdrawn) The system according to claim 24, wherein the medical device is an Automatic External Defibrillator (AED).
- 26) to 37) (Canceled)

The following Claims 38-43 are the claims involved in the appeal.

- 38) (Previously presented) A method for providing instruction on the use of a medical device to a user computer, the method comprising:
- a) providing a medical device control object in a first graphical user interface, the medical device control object simulating a control of the medical device;
 - b) providing a medical device first aid instrument object in the first graphical user interface or a second graphical user interface, the medical device first aid object simulating a first aid component of the medical device;

- g) allowing a trainee to interact with the medical device control object and medical device first aid instrument object by manipulation of the displayed medical device control object and medical device first aid instrument object in the first or second graphical user interface; and
 - c) providing feedback in response to interacting with the medical device control object and medical device first aid instrument object, the feedback indicating the correctness of the interaction with the medical device control object and the medical device first aid instrument object.
- 39) (Original) The method according to claim 38, wherein the medical device is an Automatic External Defibrillator (AED).
- 40) (Original) The method according to claim 38, further comprising:
- d) providing an audio, the audio disclosing instructional information related to the medical device.
- 41) (Previously presented) The method according to claim 38, further comprising:
- d) providing text description of one or more operational steps pertaining to the medical device.
- 42) (Previously presented) The method according to claim 41, further comprising:
- e) providing one or more still images illustrating the concept disclosed by the text description of the one or more operational steps.
- 43) (Previously presented) The method according to claim 41, further comprising:
- e) providing a video illustrating the concept disclosed by the text description of the one or more operational steps.
- 44) (Withdrawn) The method according to claim 1 wherein the interactive simulation object comprises a medical device control object.

45) (Withdrawn) The method according to claim 1 wherein the interactive simulation object comprises a medical device first aid instrument object.

46) (Withdrawn) The method according to claim 14 wherein the interactive simulation object comprises a medical device control object.

47) (Withdrawn) The method according to claim 14 wherein the interactive simulation object comprises a medical device first aid instrument object.

48) to 49) (Canceled)

APPENDIX B: EVIDENCE APPENDIX

None. No extrinsic evidence has been submitted by either party in this case.

APPENDIX C: RELATED PROCEEDINGS

None. There are no related proceedings.